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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/761,237	WENDEL ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed December 22, 2008 has been entered. Claims 1-22 are cancelled. New claims 35-40 have been added. Claims 23-40 are under consideration in this office action.

Response to Arguments

2. Applicant's arguments filed December 22, 2008 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 23 and 35 recites the limitation "the substance" in the claims. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 23-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Livesey et al., (US Patent 5,364,756 published Nov. 15, 1994).

Claim 23 is drawn to a method for testing blood for reaction to a substance comprising the steps of: selecting a cryopreserved unit dose of a blood product and a cryopreservative from among a plurality of identical cryopreserved unit doses obtained from a single or pooled sample of blood taken from a human or animal; thawing the cryopreserved unit dose; contacting the thawed, cryopreserved unit dose with the substance; and determining, by biological, physical, chemical, or physicochemical means, whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction.

Claim 35 is drawn to a method for testing blood for reaction to a substance comprising the steps of: selecting a cryopreserved unit dose of a blood product and a cryopreservative from among a plurality of identical cryopreserved unit doses obtained from a single or pooled sample of blood taken from a human or animal; thawing the cryopreserved unit dose; contacting the thawed, cryopreserved unit dose with the substance; and determining, by biological, physical, chemical, or physicochemical means, whether leukocytes in the unit dose react with the substance in an immunofunctional, toxic, or modulatory blood reaction.

Claims 24 and 36 are drawn to the blood product comprising leukocytes. Claims 25 and 37 are drawn to the blood product comprising whole blood. Claims 26-28 and 38-40 are drawn to the blood product further comprising clotting inhibitors. Claims 29-34 are drawn to the blood product further comprising diluents.

Livesey et al., teach methods for cryopreserving by preparing a cryosolution which includes a buffer, one or more cryoprotectants and a suspension of biological material (col. 3, lines 51-56). Livesey et al., teach the preservation of red blood cells, platelets, leukocytes, Factor VIII, marrow cells, and other material (col. 4, lines 57-64). Livesey et al., teach human erythrocytes are freshly obtained from donors, collected in anticoagulant or erythrocytes are processed from standard blood bank supplies (col. 7, lines 63-68). Example 4 teaches the preservation and storage of human erythrocytes. Example 4 teaches thawing the erythrocytes where a rehydration substance was added. Livesey et al., teach contacting the thawed cryopreserved unit with adsol buffer or dextran and buffer. Livesey et al., teach determining whether the unit dose comprising blood product reacts with the substance by assessing morphology using phase contrast microscopy. Livesey et al., teach after storage and assay evaluations the effectiveness was evaluated (col. 22-23).

Therefore Livesey et al., teach the instant claims.

Response to Arguments

5. Applicant's arguments have been fully considered but they are not persuasive. Applicants argue that Livesey's assessing the rehydration-substance-containing

erythrocyte samples for morphology, using phase contrast microscopy, determines neither (1) whether the erythrocyte "reacts with" the substance nor (2) whether there is "an immunofunctional, toxic, or modulatory blood reaction" (between the erythrocyte and the substance), i.e., as opposed to what occurs as recited in the determining-step limitation on the rejected claims.

However, the claims recite contacting the thawed, cryopreserved unit dose with the substance. Livesey et al., teach contacting the substance, adsol or dextran with the unit dose. The claims then require determining whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction. Livesey et al., teach determining whether the unit dose reacts with the substance (adsol or dextran) in an immunofunctional, toxic, or modulatory blood reaction (rehydration). Livesey et al., teach reconstitution/rehydration where the freezing and drying of biological substances imparts great physical stress upon the bonding forces which normally stabilize macromolecular conformations and a consequence of the procedure includes dissolution of membrane structure, enzymatic inactivation and denaturation (col. 17-18, lines 50-25). Livesey et al., teach assessing morphology and other assay evaluations to determine (by physical or physiochemical means with microscopy) the whether the unit dose reacted with the substance. contacting the substance, adsol or dextran with the unit dose. Therefore contrary to applicants assertions, Livesey et al., meets the claim limitations.

Applicants urge that claims 24, 25, 27, and 30-34 are independently novel over Livesey, under § 102(b). Livesey neither teaches nor suggests the blood product being

leukocytes or whole blood. However, contrary to applicants' assertions, Livesey et al., specifically teach obtaining fresh from donors, collected in anticoagulant and processed from standard blood bank supplies along with the preservation of leukocytes. It is noted that whole blood is what is collected from donors. Therefore contrary to applicants assertions, Livesey et al., meets the limitations of the claims. Thus applicants' arguments are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 23-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al., (US Patent 4,731,330 published March 15, 1988) in view of Livesey et al., (US Patent 5,364,756 published Nov. 15, 1994).

Claim 23 is drawn to a method for testing blood for reaction to a substance comprising the steps of: selecting a cryopreserved unit dose of a blood product and a cryopreservative from among a plurality of identical cryopreserved unit doses obtained from a single or pooled sample of blood taken from a human or animal; thawing the cryopreserved unit dose; contacting the thawed, cryopreserved unit dose with the substance; and - determining, by biological, physical, chemical, or physicochemical

means, whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction.

Claim 35 is drawn to a method for testing blood for reaction to a substance comprising the steps of: selecting a cryopreserved unit dose of a blood product and a cryopreservative from among a plurality of identical cryopreserved unit doses obtained from a single or pooled sample of blood taken from a human or animal; thawing the cryopreserved unit dose; contacting the thawed, cryopreserved unit dose with the substance; and determining, by biological, physical, chemical, or physicochemical means, whether leukocytes in the unit dose react with the substance in an immunofunctional, toxic, or modulatory blood reaction.

Claims 24 and 36 are drawn to the blood product comprising leukocytes. Claims 25 and 37 are drawn to the blood product comprising whole blood. Claims 26-28 and 38-40 are drawn to the blood product further comprising clotting inhibitors. Claims 29-34 are drawn to the blood product further comprising diluents.

Hill et al., teach the preparation and use of whole blood samples for use in other assays in which whole blood control samples are advantageous (col. 2, lines 17-23). Hill et al., teach whole blood samples comprising lyophilized mixtures or heparinized plasma samples which prevent coagulation (col. 2, lines 48-56). The sample is prepared from either human or non-human mammalian blood (col. 3, lines 10-12). Hill et al., teach other diluting substances (col. 3, lines 25-45). Hill et al., teach freezing the blood to prevent deterioration (col. 4, lines 10-15). Hill et al. teach convenient means

for quick-freezing the samples are lyophilized to maintain maximum stability (col. 5, lines 31-35). Hill et al., teach freezing the samples by subjecting them to low temperatures (col. 7, lines 23-26). Hill et al., specifically teach using the samples as a control within a prothrombin time test (col. 5, lines 47-50). The sample is reacted with reagents to produce a detectable signal thereby teaching an immunofunctional or modulatory blood reaction (col. 5, lines 50-68). Hill et al., also teach the control samples being modified to contain other analyte; analyzing the blood samples; and measuring any variation wherein the analyte was added earlier within the process (col. 6, lines 25-35). However, Hill et al., do not teach cryopreserving the units of blood.

Livesey et al., teach the desire to preserve biological material at conditions making them useable for future use is well known (col. 1, lines 30-33). Livesey et al., teach the field of cryopreservation and stabilization wherein the sample is treated with a cryopreservative while preventing irreversible damage due to the multiplicity of changes that occur during cooling and preserving the condition of the sample following cooling (col. 2, lines 25-40). Livesey et al., teach advancements in cryopreservation without overt disruption or destruction of the morphological characteristics of the ultrastructure of the sample (col. 3, lines 22-26).

Therefore it would have been prima facie obvious to modify the method for testing blood for reaction to a substance comprising the steps of: - selecting a frozen unit dose of a blood product and from among a plurality of identical unit doses obtained from a single or pooled sample of blood taken from a human or animal; thawing the frozen unit dose; contacting the thawed unit dose with the substance; and determining,

by biological, physical, chemical, or physiochemical means, whether the unit dose reacts with the substance in an immunofunctional, toxic, or modulatory blood reaction as taught by Hill et al., wherein the modification incorporates the cryopreservation techniques as taught by Livesy et al., in order to provide a cryopreserved unit which prevents irreversible damage due to the multiplicity of changes that occur during cooling and quick-freezing. No more than routine skill would have been required at the time of applicants' invention to incorporate well known cryopreservation techniques and cryopreservatives into the method of Hill et al., with no change in their respective functions, especially when the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Furthermore, the claim would have been obvious because the substitution of quick-freezing for cryopreservation would have yielded predictable results to one of ordinary skill in the art at the time of the invention while preserving the condition of the thawed sample; and one of ordinary skill in the art would have a reasonable expectation of success by exchanging the freezing techniques because the art advantageously teaches the benefits of cryopreservation over freezing as preventing disruption or destruction of the morphological characteristics of the ultrastructure of the sample.

Response to Arguments

7. Applicant's arguments have been fully considered but they are not persuasive. Applicants argue that Hill et al.,

In response to applicant's arguments against the Hill reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is agreed that Hill et al., teach freezing the blood to prevent deterioration by quick-freezing and lyophilzation of samples to maintain maximum stability; and Hill et al., do not recite cryopreserving the blood. But applicant is reminded that the rejection is based upon Hill et al., in view of Livesey et al. And Livesey et al., teach the desire to cryopreservation of preserve blood product biological material. Therefore applicants' argument is not persuasive.

Applicants' argue that Livesey et al., provide no teaching or suggestion to supply the aforesaid deficiencies in Hill et al., In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hill et al., clearly recite the desire or need to freeze blood in order to prevent its deterioration. Thus, all the claimed elements, such as cryopreservation where known in the prior art and one skilled in the art could have combined freezing and cryopreservation by well known methods with no change in their

respective functions, and the combination of cryopreserved blood product would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Thus, applicants' argument is not persuasive.

Applicants urge that claims 24, 25, 27, and 30-34 are independently novel over Hill et al., in view of Livesey et al., because neither teach nor suggest the blood product being leukocytes or whole blood. However, contrary to applicants' assertions, Hill et al., teach the preparation and use of whole blood samples from humans. Livesey et al., specifically teach obtaining fresh from human donors, processed from standard blood bank supplies and the preservation of leukocytes. Therefore the art clearly teaches blood samples obtained from a single or pooled sample taken from a human or animal. Therefore contrary to applicants' assertions, Hill et al., in view of Livesey et al., meet the limitations of the blood product being leukocytes or whole blood. Thus applicants' arguments are not persuasive and the rejection is maintained.

Conclusion

8. No claims allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645